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1638

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RE: Patent Application for) Date: September 15, 2003
Inventor(s): Carlone) Art Unit: 1638
Serial No.: 09/811,048) Examiner:
Filed: March 15, 2001)
Title: INBRED CORN LINE G3601) Action: **Response to Office Action**

To: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

This is in response to the office action dated 05/14/03, which was nonfinal. An extension of time is included as are the marked claims.

The Applicant respectfully thanks the Examiner for removing the objections to claims 4, 12, 15, and 16.

Information Disclosure Statement

The reference M.P Rolston is not believed to add any disclosure that the Examiner would consider relevant to the examination of the claims.

Claims Objections

The misspelling in claim 18 has been corrected.

Claim Rejections –35USC §112

Regarding the recitation of 'G3601' the Examiner has agreed to hold the rejection in abeyance. The Examiner has noted that the deposit statement in the specification does not state that the viability of the biological material will be tested at the time of deposit, as required by 37 CFR 1.807. The Applicant through its attorney herein states that if the biological material is deposited the viability of the material will be tested at the time of deposit, as required by 37 CFR 1.807.

Regarding the recitation of "protoplasts" in claim 4, this claim has been amended according to the Examiner's suggestion.

Regarding claim 18 the element that is missing has been added. In the maize seed industry there has not yet been a method by which hybrid seed can be manufactured on a large scale that would not de facto incorporate some level of inbred seed in the hybrid production. Therefore in most instances when hybrid seed is planted a trace amount of

inbred seed , which is commingled, with the hybrid seed would also be planted. The element of inbred seed within the hybrid seed has been incorporated within the claim and the Examiner is kindly requested to reconsider the rejection in light of this change in the claim recitation.

The Examiner suggests that claim 19 incorporates inbred seed that is not the inbred seed according to claim 1. Hopefully, the amendment to the claim makes clear that the inbred is the inbred of the present invention and it is an inbred seed according to claim 1.

In claim 9, the Examiner indicated that words appear to be missing between "number X" and "the process of" in line 3. The Applicant has amended claim 9 to include the word "in". This should provide the missing word.

In claim 12, 13 and 15, 16: the claims are indefinite because the claims broaden the scope of the original claim 1. The applicant has amended some of the claims 12-16.

Written Description

The Examiner rejected claims 6 -17 as containing subject matter, which was not, described in the specification in a way as to show that the applicant had possession of the invention. The Examiner is saying that the description of claimed inventions are not for those in the art to determine. However, the applicant points out that the 37 CFR 1.71 requires that the specification must include a written description of the invention or discovery.... Full, clear concise and exact terms as to **enable any person skilled in the art or science to which the invention ...appertains,...to make and use the same.** Additionally, in S3 INC. v. NVIDIA Corp., 259 F.3d 1364,59 USPQ2d 1745 (Fed. Cir. 2001). The court cited other cases stating " The law is clear that patent documents need not include subject matter that is known in the field of the invention and is in the prior art, for patents are written for persons experienced in the field of the invention. See Vivid Technologies, Inc. v. American science and Engineering, Inc. 200 F. 3d. 795, 804 53 USPQ2d 1289, 1295 (Fed Cir. 1999) ('patents are written by and for skilled artisans')

Later in the decision the same court cited *Atmel Corp.*, 198 F.3d at 1382, 53 USPQ2d at 1230 (Fed. Cir. 1999) (The specification would be of enormous and unnecessary length if one had to literally reinvent and describe the wheel') *W.L. Gore & Assoc., Inc.*, 721 F.2d 1540, 1556, 220 USPQ 303, 315 (Fed. Cir. 1983) (Patents are written to enable those skilled in the art to practice the invention and not the public.').

Descriptions of claimed inventions must be supplied by the specification. *Spectra-Physics Inc. v. Coherent, Inc.* 827 F.2d 1524, 1536, 3 USPQ2d 1737, 1745 (Fed Cir. 1987) states there is no statutory requirement for the disclosure of a specific example. A patent specification is not intended nor required to be a production specification.

In the specification in the background the applicant has on the bottom of page 4 indicated that new biotechnology techniques such as Microsatellites, RFLPS, RAPDS and the like are tools that can be used in breeding. Clearly, the use of markers to identify parentage of plants for use in breeding or simply for pedigree identification has long been known and practiced by the person of ordinary skill in the art of plant breeding.

In this specification the applicant has indicated an older method of identifying the genotype of inbred. This is shown in Table 2 as the isozyme data of the inbred. The Examiner, however, is requiring that the Applicant provide the morphological and physiological traits of these hybrids. The applicant questions why this is necessary. What statutory requirement is there that requires the morphological and physiological traits of the hybrid to be listed. This is especially the question when the information is not need to make a hybrid (the inbred seed is to be deposited) and the information is not need to identify if a hybrid has the inbred in its parentage. The Examiner is also suggesting that marker data, which is necessary for a written description, is not given. However, marker data is given in the specification as isozymes. This is the original and oldest form of marker data. Newer types of marker data is not shown. Exactly which type of marker data does the Examiner wish to see, RFLP's , AFLPs, RAPDS, Microsatellites, SNP's? This new marker data (from whatever marker set the Examiner thinks is the right one) does not need to be

shown to comply with the written description requirement. Such data, even if supplied, would not be very useful. The ordinarily skilled person works with their own marker types and their own collection of such markers.

Taking genetic information from the plant of the deposited seed and running a fingerprint of such maize genetic material with your own chosen marker set does not require undue experimentation for someone of ordinary skill in the art. This marker information will relate to the other marker information that may have previously been gathered on other inbreds with the same markers. To analyze the marker data to determine a relationship between the inbred and a hybrid can be done with an off the shelf SAS computer program that has been employed for this very purpose for the last ten years or more. The claims to hybrids are in full compliance with the written description requirement, without any morphological and physiological traits of the hybrid being listed in the specification. Please correct an error from the previous office action response. That response indicated at least 15,000 hybrid seed were in existence prior to the filing of the application. The previous office action also states 30 million and 26 million seeds were in existence prior to the filing of the application. Please ignore 30 million and 26 million seeds, even though the actual hybrid seed count prior to filing was closer to the million mark than the 15,000. The actual estimated number of seeds for the trials was not calculated. So the 15,000 estimate which substantially underestimates the actual number of hybrid seeds is being used.

The F1 hybrids claimed in the present invention have 50% of the genotype of the inbred of the present invention and 50% of the other inbred. Since the inbred seed of the present invention is to be deposited, a fingerprint of the inbred is a simple procedure to run. When this inbred fingerprint is compared with the fingerprint of the hybrid the ordinarily skilled person in the art can easily identify the parentage of the F1 hybrid plant. In fact the parentage of humans is calculated in a similar manner. If marker technology such as RFLP is sufficiently exacting technology to determine a child support order it should be sufficient to determine maize parentage for a patent.

The applicant has complied with the guidelines. The guidelines state that:

“...The written description requirement, a question of fact, ensures that the inventor conveys to others that he or she had possession of the claimed invention; whereas, the enablement requirement, a question of law, ensures that the inventor conveys to others how to make and use the claimed invention.”... “to satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways including description of an actual reduction to practice.” (*If affidavits by one skilled in the art as to his/her **conclusion that the inventor had possession of the claimed invention** at the time of filing would be helpful in this matter the Applicant will provide such affidavit upon the Examiner’s request.*)

In J.E.M. Ag Supply, Inc. v. Pioneer HI-Bred International, Inc. 534 U.S. (2001), the court stated, “A patent for an inbred corn line protects both the seeds and plants of the inbred line and the hybrids produced by crossing the protected inbred line with another corn line. See e.g. U.S. Patent No. 5,506,367, col. 3, App. 42.” The information provided in the written description of that patent specification is the same in scope or at least very similar in scope to the application at hand. Thus it is difficult to see why the written description requirement of an original claim is not met. Persons skilled in the art would recognize in the disclosure a description of a hybrid seed or plant made with the inbred.

The Claims have been amended according to the Examiner’s suggestion to reflect the type of mutated gene and the transgene that is introduced. The support for this language is in the first paragraph following the last Table in the specification.

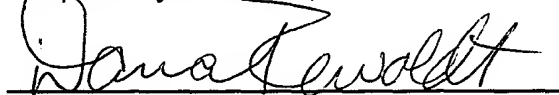
35 USC. §112, first paragraph

The Examiner rejected claims 1-18 and claims 19 and 20 under 35 USC. §112, first paragraph, as failing to comply with the enablement requirement. The statement made above should place the application in substantial compliance with this requirement.

In paragraph seven the Examiner acknowledges the novelty and the nonobviousness of claims 1-5 and 18. The Applicant thanks the Examiner for this acknowledgment. But the Applicant would like to direct the Examiner's attention to the discussion above concerning the no necessity of including morphological and physiological properties of the hybrids. The hybrids would and should be identified by pedigree and by genotype. Therefore the ordinarily skilled person in the art will not have an issue determining if the hybrid had G4901 or G3601 or yet another inbred as a parent. The morphological and physiological properties of the hybrids are simply not needed to determine if the hybrid is covered by the specification. The morphological and physiological properties of the hybrids are not needed to make the hybrid. The morphological and physiological properties of the hybrids are not needed to analyse the parentage of the hybrid.

A hybrid made without the inbred of the present invention in its ancestry simply could not infringe the claim. Such a hybrid therefore does not anticipate the claim and does not make the claim nonobvious. The Examiner is respectfully requested to reconsider this rejection in light of the information provided. (If it would be helpful the applicant can supply affidavits from those skilled in the art concerning whether a hybrid made without the present inbred would not make the claims directed to such a hybrid either obvious or lacking in novelty.)

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Dana Rewoldt", written over a horizontal line.

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